Official Title: Effect of a Navigator Program on Post-Hospital Outcomes for Homeless Adults: A Pragmatic Randomized Controlled Trial

Brief Title: Navigator Program for Homeless Adults

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Abstract

Individuals experiencing homelessness often have complex health and social needs. They also face disproportionate systemic barriers to accessing healthcare services and social supports. Some of these barriers include not having a primary care provider, needing to meet other competing priorities, and difficulties affording medications. These barriers contribute to discontinuities in care, poor health outcomes, and high acute healthcare utilization after hospitalization among this population. This study aims to evaluate the effect of a unique case management intervention – the Navigator program – on post-hospital outcomes for individuals experiencing homelessness after hospitalization. This study will examine follow-up with primary care providers, acute healthcare utilization, quality of care transition, and overall health for those receiving the Navigator program compared to those receiving usual care over 180-days after hospital discharge.

Background and Rationale

In 2014, there were 235,000 Canadians who were experiencing homelessness, of which 27.3% were women, 18.7% were youth, and a growing number were identifying as Indigenous, a veteran, and/or LGBTQ.[1] Homeless individuals experience disproportionate intersecting physical, mental, and social burdens that greatly increase morbidity and mortality relative to the general population.[2–4] For example, rates of acute and chronic physical health problems, trauma, mental illness, and substance use are much higher among homeless adults.[5,6] These complex social- and health-related needs often require support from traditional healthcare providers and multiple community services, including case managers, housing workers, and harm reduction counsellors.[7,8]

Despite these health inequities, homeless individuals often experience substantial barriers to obtaining healthcare and frequently suffer from many unmet health needs.[9–11] Many have other immediate competing priorities such as securing food and shelter that preclude consistent engagement with healthcare services.[12] Homeless individuals are met with considerable systemic challenges in relation to healthcare access, including financial barriers to transportation and medication and difficulty obtaining government-issued identification.[13] Studies have shown that homeless individuals are much less likely to have a primary care provider (PCP) or receive outpatient care compared to the general population.[14,15] Much literature has demonstrated that continuity of care provided by PCPs contributes to better health outcomes, a greater focus on the social determinants of health, and reductions in episodic care at emergency departments (EDs) and hospitals.[16–18] Indeed, homeless adults rely heavily on acute care services, resulting in a

higher rate of ED use and hospitalization among homeless adults compared to the general population.[19–23]

Studies across the US and Canada have shown high rates of hospital readmission rates among homeless adults compared to that of the general population.[22–26] Care providers and policymakers have long sought to reduce readmissions given that they are suboptimal from a patient perspective and financially costly from a societal perspective.[27,28] Many readmissions for homeless individuals are thought to be preventable with more complete treatment and better coordination of health and social services following discharge.[29,30] Although the literature is inconclusive, studies have shown that leaving against medical advice and not having a PCP post-discharge are associated with readmission among homeless adults.[24,31,32] While patients usually require ongoing healthcare after discharge, much of their needs can be treated or well-managed by PCPs and outpatient services in the community.[20,33] Qualitative studies have also revealed that homeless individuals face diverse health and social challenges following discharge from the hospital. Some of these include difficulties storing medication, inability to find shelter, not being provided appropriate discharge instructions, and juggling competing priorities such as food insufficiency.[34–37] Altogether, systemic barriers to care, competing priorities, and poor care transition all contribute toward poor post-hospital outcomes and reliance on acute healthcare services among homeless individuals.

Case managers are a main component of care for homeless individuals, serving as central points of contact to coordinate health and social services.[38] The Case Management Society of America defines case management as a "collaborative process of assessment, planning, facilitation, care

coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote patient safety, quality of care, and cost-effective outcomes." Case management programs have been adapted and implemented for several subgroups of homeless individuals, including frequent users of acute healthcare services and those with complex needs and mental illness.[39–41] A systematic review reported that general case management for homeless individuals is effective in improving housing stability, reducing substance abuse, and removing barriers to securing employment.[42] Other systematic reviews and studies have found that case management programs are effective in reducing hospitalization and ED use, decreasing length of hospital stay, and improving patient outcomes among other populations.[43–45]

This present study builds upon a recent prospective cohort study conducted by our team that identified factors contributing to poor post-hospital outcomes among homeless adults. We identified that having an active case manager, sending the discharge summary to patient PCPs, and informal support are associated with reduced readmissions among this population.[46] We have used these findings to develop a hospital-based intervention. Accordingly, this study seeks to investigate the effectiveness of an adapted Critical Time Intervention (CTI) case management program – the Navigator program – in improving post-hospital outcomes among homeless adults admitted to St. Michael's Hospital. The Navigator program features a Homeless Outreach Counsellor– whose role is to create strong links between community services and patients through regular contact, supporting patients in following their post-discharge care plans, and helping patients in meeting their competing priorities. The Homeless Outreach Counsellor meets patients upon admission to a medical ward at St. Michael's Hospital (General Internal Medicine

service, any Medicine subspecialty service, the Cardiac Intensive Care Unit, and the Medical Surgical Intensive Care Unit) and continues to work with them for up to 90-days post-discharge. The first Homeless Outreach Counsellor position was created in February 2019 and has since been expanded and adapted through conversations with community partners and medical staff. The Navigator Program is fully funded by the St. Michael's Hospital Foundation and now includes two full-time Homeless Outreach Counsellors and a part-time Program Coordinator. Ultimately, the goal of the Navigator program is to support discharged patients overcome systemic barriers and discontinuities in care that often result in poor health and high acute healthcare utilization among individuals experiencing homelessness.

Study Objectives

This study seeks to evaluate the effectiveness of the Navigator program in improving post-hospital outcomes among homeless adults using a randomized controlled trial design. It will specifically evaluate outcomes relating to follow-up with a PCP, acute healthcare use, social service use, continuity of care, patient perception of care transition, and overall health following discharge. Results from this study will provide insight into how health systems can provide better post-discharge care to homeless individuals to improve patient outcomes and reduce acute healthcare use.

Research Questions and Study Hypotheses

We hypothesize that patients receiving the Navigator program, compared to usual care participants, will:

1. Be more likely to follow-up with a primary care provider within 14-days of hospital discharge (primary outcome)
2. Have reduced composite all-cause hospital readmission or mortality within 30-, 90-, and 180-days post-discharge (secondary outcome)
3. Have reduced number of ED visits within 30-, 90-, and 180-days post-discharge (secondary outcome)
4. Have reduced number of days in hospital within 30-, 90-, and 180-days post-discharge (secondary outcome)
5. Have a better self-reported experience of care transition after hospital discharge (secondary outcome)
6. Have a greater reduction in competing priorities at the time of the 30-day interview relative to baseline (secondary outcome)
7. Have a greater increase in health status at the time of the 30-day interview relative to baseline (exploratory outcome)
8. Be less likely to leave against medical advice at index discharge (exploratory outcome)
9. Have greater medication adherence at the time of the 30-day interview (exploratory outcome)
10. Be more likely to be connected to a case manager at the time of 30-day interview (exploratory outcome)
11. Be more likely to attend any non-PCP healthcare appointments within 180-days post-discharge (exploratory outcome)
12. Have a longer time to all-cause hospital readmission or mortality after index discharge (exploratory outcome)

Research Approach

We will use a pragmatic randomized controlled design to conduct a clinical trial evaluating the effectiveness of the Navigator program. Adults experiencing homelessness on the General Internal Medicine service, any Medicine subspecialty service, the Cardiac Intensive Care Unit, and the Medical Surgical Intensive Care Unit at St. Michael's Hospital will be eligible to participate in the study. After completion of eligibility screening, enrollment, and the baseline interview, participants will be randomized to either receive the Navigator program or usual care (Appendix G, Eligibility Screening). The research team will conduct another interview with participants around 30-days after hospital discharge to assess healthcare use, connection to community services and supports, care transition experience, health status, and competing priorities. The research team will conduct one chart review after hospital discharge to ascertain characteristics of the index admission, information about the discharge, and participant health information. The research team will conduct a second chart review 180-days after hospital discharge to determine if patients visited the ED or were hospitalized at any hospitals in the area, including St. Michael's Hospital, St. Joseph's Hospital, Toronto General Hospital, Toronto Western Hospital, Mount Sinai Hospital, and Michael Garron Hospital. During this time, with participant consent, the research team will also contact primary care providers and other healthcare providers to confirm appointment attendance. Finally, patient consent will be requested for administrative data linkage to determine any acute healthcare use prior to the index hospital admission and after hospital discharge.

Study Eligibility and Recruitment

Potential participants will be recruited by the research team on weekdays. The research team will identify potentially eligible participants through regular discussions with clinical staff about patients admitted to the General Internal Medicine service, any Medicine subspeciality service, the Cardiac Intensive Care Unit, and the Medical Surgical Intensive Care Unit at St. Michael's Hospital. Once identified, a member of the patient's circle of care will obtain permission from the patient to introduce the patient to the research staff. Research staff will confirm patient eligibility and explain the purpose, process, risks, and benefits of the study to potential participants. Participants can then choose to participate in the study by providing written informed consent.

Inclusion Criteria

To be eligible for the study, patients must meet the following criteria during their index admission:

- 18 years of age or older
- Have an unplanned admission for any medical cause to the General Internal Medicine service, any Medicine subspecialty service, the Cardiac Intensive Care Unit, and the Medical Surgical Intensive Care Unit
- Identified as being homeless at the time of admission or anytime during the index hospital admission. This includes patients who are: *unsheltered (*absolutely homeless and living on the streets or in places not intended for human habitation), *emergency sheltered* (staying in overnight shelters for people who are homeless, as well as shelters for those impacted by family violence), or *provisionally accommodated* (whose accommodation is temporary or lacks security of tenure).[47]

Exclusion Criteria

Patients will be excluded from the study if they meet any of the following criteria:

- Unable to provide informed consent to the study
- Previously received services from the Homeless Outreach Counsellor within 6 months of admission

Given the pragmatic nature of this study, all participants who survive to discharge from the index hospitalization will be retained in the study, regardless of discharge location. For example, participants discharged to hospice, nursing homes, rehabilitation facilities, or other institutional settings (e.g. jail or palliative care) will be included in the study. Participants in both arms of the study will be able to access any other hospital-provided and community support services normally available to them, including the Coordinating Access to Care for People Experiencing Homelessness (CATCH) program.

When the study begins, access to the Homeless Outreach Counsellors will be limited to only participants in this study who are randomized to the Navigator program group. However, there will be two exceptions in which the Homeless Outreach Counsellors may work with patients outside of the study. First, prior to the beginning of the study, the Homeless Outreach Counsellors will have been working with some patients. These patients may continue to receive services from the Homeless Outreach Counsellors until 90-days post-discharge but will be ineligible to participate in the study until they have had no contact with the Homeless Outreach Counsellors for another 6 months. Second, the Homeless Outreach Counsellors may provide

services to patients with persistent and irreversible conditions (e.g. dementia) who are incapable of providing informed consent and therefore excluded from participating in this study.

Capacity to Provide Informed Consent

We anticipate that most patients will be able to understand and participate fully in the consent process. However, if there are any doubts, an Additional Consent Measures Checklist will be used to confirm participants' understanding of key aspects of the letter of information and consent form prior to signing (Additional Consent Measures Checklist, Appendix F). Additionally, during recruitment and interview scheduling, we will offer access to a professional interpreter for anyone with difficulty communicating in English. In these cases, the interpreter will be asked to sign the "Interpreter Declaration" section of the consent form. If the interpreter is providing interpretation services remotely, the research assistant will ask for verbal consent to sign the consent form on behalf of the interpreter.

Procedure for Verbal Informed Consent

Upon participant request or in the event of special circumstances (e.g. COVID-19 precautions), we will offer patients the option to provide verbal informed consent over the phone. Participants will be read the letter of information over the phone and will be provided with a written copy in-person or by email. If participants provide their informed consent, the research assistant will sign two copies of the consent form on the participants' behalf. One completed form will be kept by the research team and another completed form will be provided to the participant.

Study Population

Characteristics of study participants are expected to be similar to what our team has found in our previous prospective cohort study of homeless adults admitted to the St. Michael's Hospital General Internal Medicine Service.[46] Of 129 participants recruited between November 2017 and February 2019, the mean age was 54.6 (SD:13.9), 101 (78%) were male, 90 (70%) were White, and 87 (68%) had a high school education or more. 45 participants (35%) had a mental health condition, 80 (62%) had documented alcohol or substance use, and 32 (25%) had a Charlson Comorbidity Index score greater than or equal to 3. Finally, the median length of hospital stay for all participants was 7 (IQR: 4-14.5) days, 30 (23%) had been admitted to the study hospital in the past 3 months, and 61 (47%) saw a case manager in the past 2 months. However, it is possible that characteristics of participants in this study may be different given that the study population will be expanded to include other Medicine services, the Cardiac Intensive Care Unit, and the Medical Surgical Intensive Care Unit

Sample Size Justification

No previous data are available to ascertain 14-day PCP follow-up rates after hospitalization among homeless individuals under usual care. However, a previous study found that 14-day PCP follow-up rates after hospitalization among low socioeconomic status (SES) patients was 48%.[48] We assume that the 14-day PCP follow-up rate after hospitalization among homeless individuals, under usual care, is around 2/3 that of low SES patients at 32%. The table below shows total sample sizes needed in each group to achieve 80% power to detect various differences in group proportions with a significance level of 0.05 using a two-sided Z-test with pooled variance.

Control 32% of participants follow-up with a PCP within 14 days of hospital discharge	**6% Risk Difference (RD)** 32%+6%=38%	**8% RD** 32%+8%=40%	**10% RD** 32%+10%=42%	**12% RD** 32%+12%=44%	**14% RD** 32%+14%=46%	**16% RD** 32%+16%=48%
Total Sample Size	1982	1128	730	512	380	292
Total Sample Size with Adjustment for 20% Attrition Rate	2478	1410	912	640	476	366

For this study, we estimate that 12% more participants allocated to the Navigator arm will follow-up with a PCP within 14-days of discharge relative to the control arm. A 12% risk difference is equivalent to a 37.5% increase in relative risk of following-up with a PCP within 14-days of discharge. With a 20% attrition rate, we estimate that 320 participants will be needed in each group – for a total of 640 participants.

Homeless Outreach Counsellor Caseload

It is anticipated that the Homeless Outreach Counsellors will always have the capacity to accept new participants during the study. Since February 2019, one Homeless Outreach Counsellor has successfully provided services to 30 active participants at one time.[46] This number is consistent with past reviews of case management.[42] Past observations have revealed that around 30 adults experiencing homelessness are admitted to the General Internal Medicine service at St. Michael's Hospital each month. With the additional Medicine services, the Cardiac Intensive Care Unit, and the Medical Surgical Intensive Care Unit, we estimate that there will be around 40 adults experiencing homelessness that will be eligible for study enrollment each month. Our

past study found an enrollment rate of 65%, meaning that around 26 participants could be enrolled into the study each month. Over 90 days, this equates to 78 total participants or 39 participants that are randomized to the intervention arm. The estimated peak of 39 participants is well within the capacity of 60 active participants between the two Homeless Outreach Counsellors.

Given that the estimated total sample size needed for the study is 640 participants, we estimate that we will require around 24 months to finish enrollment for the study given a monthly enrollment rate of 26 participants per month.

Randomization

Following enrollment, participants will be randomized by a third-party internet randomization service ("randomize.net"). The resulting study allocation will be displayed on the tablet of the research staff who oversaw patient enrollment and communicated to participants. The randomization service will assign participants to either the intervention or the usual care arm using permuted-block randomization, with a 1:1 allocation ratio and random permuted blocks. This technique will maintain balanced group sizes between the intervention and usual care arms at intermediate points in the recruitment process and minimize the possibility of the research team predicting study allocation.[49] The research team will have no role in determining the study allocation of participants.

Blinding

Due to the active involvement of the Homeless Outreach Counsellor in the intervention and the collaborative relationship between the Homeless Outreach Counsellor and the participant's circle of care, it will not be possible to blind participants, the Homeless Outreach Counsellors, or the participant's circle of care to the allocation of participants. However, several measures will be put in place to blind specific members of the research team, in particular the data collectors, data analysts, and outcome adjudicators.

There are three circumstances where a member of the research team will not be blinded to the study allocation of certain participants. First, the research assistant who revealed study allocation to the participant after enrollment will no longer be blinded to the study allocation of that particular participant. To mitigate potential bias, this research assistant will not be involved in the 30-day interview for that particular patient. Second, there is a possibility that research assistants might become unblinded during chart reviews if they come across information about the Homeless Outreach Counsellor. However, the chart abstraction process only involves extraction and not interpretation of objective data. If a research assistant becomes unblinded during discharge chart review, this research assistant will not be involved in the 30-day interview for that particular patient. Third, the Principal Investigator of this study is a Staff Physician on the General Internal Medicine service at St. Michael's Hospital. There is a possibility that he will become unblinded to study allocation of certain participants while on service. To mitigate potential bias, the Principal Investigator will only be involved in the analysis of de-identified data and he will not be involved in patient interviews and data collection. Unblinding events are not expected to occur during the 30-day interview given that it has been designed such that no

questions should prompt participants to reveal their study allocation. No other unblinding events are expected during hospitalization given that the research team – outside of the Principal Investigator - is not involved in participant care or have direct participant interaction outside of the 30-day interview.

After enrollment, participants will be assigned a unique study identifier number which will be used in the data collection and analysis processes. A Master Linking Log with participant identifiers will only be made available to a designated member of the Survey Research Unit who will have no contact with participants and will not participate in any data collection (Master Linking Log, Appendix E). Research assistants conducting interviews and performing chart reviews will only have access to the name of participants, their unique study identifier, and information to access health records with participant consent.

The Intervention

Active Intervention

Participants in the intervention arm will be assigned to one of two Homeless Outreach Counsellors following randomization. The Navigator program is an adaptation of the Critical Time Intervention (CTI) model of case management. CTI is a time-limited case management program which delivers focused case management at critical times or situations in the lives of clients, such as transitioning from hospital care to community care.[42] CTI has been previously shown to improve housing stability, health outcomes, and psychiatric symptomatology for adults experiencing homelessness.[50–52]

The Homeless Outreach Counsellors will connect with participants as soon as possible during their admissions and will provide support up to 90 days after hospital discharge. The main role of the Homeless Outreach Counsellor is to support continuity and comprehensiveness of care by helping participants follow their post-discharge plans and facilitating strong links with community-based health and social services. The Homeless Outreach Counsellor also helps address specific needs of participants, develop comprehensive care plans with members of patient's multidisciplinary circle of care, and facilitate the transition of clients to long-term community-based health and social services. Day-to-day activities of the Homeless Outreach Counsellor include maintaining therapeutic rapport with participants to facilitate post-discharge plans, helping patients attend healthcare appointments post-discharge, and providing outreach support to connect participants with resources and services in the community. The intensity and types of support from the Homeless Outreach Counsellor will be tailored to the specific needs of the participant. The Homeless Outreach Counsellor will document all interactions with participants, healthcare teams, and community services in case notes developed specifically for the Navigator program.

Usual Care

Participants in the usual care arm will be discharged without transitional case management from the Homeless Outreach Counsellor. However, participants on the General Internal Medicine service will still receive support from Care Transition Facilitators (CTFs) and participants on other services will still receive support from social workers. CTFs work with patients during their hospital stay to arrange discharge plans and make follow-up arrangements. However, unlike the Homeless Outreach Counsellors, CTFs do not work with patients after hospital discharge.

The typical discharge process also involves counselling from the discharging physician and healthcare team, who make recommendations or appointments for follow-up care as needed. Moreover, participants will be provided with a written discharge summary and prescription(s) as needed. If the participant has a PCP, they may also receive a copy of the discharge summary.

Methodology

Interviews will be conducted with all participants at baseline and around 30-days post-discharge. The following categories of information will be collected with the corresponding survey instruments:

1. Demographic information, including age, gender, race/ethnicity, education level, sources of income, and housing status (only at baseline)
2. Healthcare use and access to healthcare, including information about PCP, past history of PCP visits, recent ED visits, and recent hospitalizations
3. Social service use, including information about encounters with case managers, housing workers, and addiction or harm reduction workers
4. Health status using the EQ5D
5. Competing priorities using the RAND Course of Homelessness Scale
6. Self-reported quality of post-hospital care transition using the CTM-3 (only at the 30-day interview)
7. Medication adherence using the Morisky Medication Adherence Scale 8 (only at the 30-day interview)

Information about number of ED visits, hospital admissions, and days in hospital in the past year and 180-days post-discharge will be collected from participant hospital charts from St. Michael's Hospital, St. Joseph's Hospital, Mount Sinai Hospital, Toronto General Hospital, and Toronto Western Hospital at 180-days post-discharge. Linkage to administrative databases at ICES will also be performed to ascertain healthcare use. Mortality data will be collected from hospital charts or follow-up with community contacts. Contact will be made with participants' primary care providers and other healthcare providers to confirm attendance of appointments. Information about the number of contacts and nature of contacts between the Homeless Outreach Counsellors and participants, community service providers, and healthcare team will be ascertained from the Homeless Outreach Counsellor.

This study is seeking approval from the Research Ethics Boards of St. Michael's Hospital, St. Joseph's Hospital, Mount Sinai Hospital, Toronto General Hospital, Toronto Western Hospital, and Michael Garron Hospital.

Outcomes

The primary outcome is follow-up with a PCP within 14-days of hospital discharge. Early primary care follow-up after hospitalization has been associated with better patient outcomes.[53–55] The definition of a PCP includes both family doctors and nurse practitioners. In-person visits (e.g., hospital clinics, shelter clinics, and community health centers), virtual encounters (with video), and phone calls (without video) will be considered as follow-up with a PCP. These modes of PCP follow-up are in line with those outlined by quality standards from Health Quality Ontario.[56] We will ascertain a PCP follow-up through both self-report by participants at the 30-

day interview and confirmation by contacting the PCP office. However, it is acceptable to confirm only with the PCP office if the participant is unreachable and also acceptable via only participant self-report if the PCP office is unreachable. If there is any discrepancy, the PCP office will take precedence over participant self-report.

Secondary outcomes include all-cause hospital readmission or mortality (composite) within 30-, 90-, and 180-days post-discharge, total number of days spent in hospital within 30-, 90-, and 180-days post-discharge, number of ED visits within 30-, 90-, and 180-days post-discharge, self-reported quality of care transition after hospital discharge, and self-reported change in competing priorities at the time of the 30-day interview relative to baseline. Measuring acute healthcare use outcomes within 30-days post-discharge is standard for such outcomes in health systems across Canada.[57] However, we will also measure acute healthcare use outcomes within 90-days and 180-days post-discharge because we observed low event rates within 30-days post-discharge in our previous prospective cohort study.[46] All acute healthcare use outcomes will not include labour/delivery visits, planned readmissions, and transfers between services within the hospital. All acute healthcare use outcomes will also be ascertained from the 30-day interview, 180-day chart review, and administrative databases at ICES. Self-reported quality of post-hospital care transition will be ascertained at the 30-day interview and competing priorities will be ascertained at both the baseline and 30-day interviews.

Exploratory outcomes include change in health status at the time of the 30-day interview relative to baseline, leaving against medical advice at index discharge, medication adherence at the time of the 30-day interview, connection to a case manager at the time of the 30-day interview, attendance of any non-PCP healthcare appointment within 180-days post-discharge, and time to

all-cause hospital readmission or mortality after index discharge. Only non-PCP healthcare appointments made by the time of discharge and written in the discharge summary from the index admission will be assessed for attendance. Time to all-cause hospital readmission or mortality will be defined as the number of days from index discharge to the first all-cause hospital readmission or mortality during the 180-day observation period. Only participants that did not previously report contact with a case manager in the 30-days prior to the baseline interview will be assessed for the connection to a case manager outcome. Health status will be measured at both baseline and 30-days interviews. All acute healthcare use outcomes will be ascertained from the 30-day interview, 180-day chart review, and administrative databases at ICES. All other exploratory outcomes will be ascertained from the 30-day interview.

Data Collection

Baseline and 30-day interviews will be conducted at baseline and around 30-days post-discharge with all study participants. Interviews will be completed by trained research assistants from the Survey Research Unit at the MAP Centre for Urban Health Solutions at St. Michael's Hospital. To minimize study attrition, at the baseline interview, study participants will be asked to provide detailed contact information, as well as the names and contact information of family, friends, and other service providers that can be contacted (with participant consent) if the research team cannot reach the participant (Contact Information Form, Appendix D). Information from the Contact Information Form will be stored securely by the Survey Research Unit.

Interviews

The baseline interview will be conducted prior to randomization and as soon as possible after participant enrollment (Baseline Admission Interview, Appendix C1). It will take approximately 30 minutes. The baseline interview must be conducted prior to discharge from the index admission and may be conducted in-person or remotely.

The 30-day interview will take place at least 30 days (but no later than 40 days) after the index admission discharge date (30-Day Interview, Appendix C3) and will take approximately 45 minutes. The 30-day interview may be conducted in-person or remotely. The participant will be given a card at discharge with the time and date of the interview and the contact information of the research team (with the EQ5D VAS scale on the back of the card for the 30-day interview). If the interview is to take place in-person, the meeting location will be set at St. Michael's Hospital or somewhere in the community that is convenient for the participant. Research staff will contact participants two weeks following discharge and the day before the interview to confirm the time, date, and meeting location.

The interviews contain validated scales and questions which were selected based on their relevance, psychometric properties, ease of implementation, and prior use in research among the homeless population. The research team will be collecting data with tablets using electronic based surveys hosted by SNAP Professional Software. Please note that SNAP Professional Software has been reviewed and approved for use by St. Michael's Hospital. The SNAP Server is owned by the Survey Research Unit and is located inside the St. Michael's Hospital network.

The following domains will be assessed in the interviews:

Domain and Selected Instrument	Instrument or Variable
Sociodemographic Variables	Research staff will collect the following information: basic demographic information (gender, race/ethnicity, partner status, education, prescription drug coverage), smoking status, housing status, and income support).
Healthcare Use and Access to Care	Research staff will collect the following information: -Name of PCP, PCP location, and last time participant visited the PCP -ED visits in the past ~30 days -Hospitalizations in the past ~30 days -Whether the participant felt they did not receive needed healthcare in the past ~30 days -Whether the participant saw a PCP within 14 days of discharge date
Social Service Use	Research staff will collect the following information: -Whether the participant is connected with a case manager, housing worker, or addiction or harm reduction worker. -How many times the participant saw any of the above service providers in the past ~30 days -Whether the participant is currently applying for any social benefits or supports
Health Status/Functional Status	**EQ-5D-3L** The EQ-5D-3L is a generic measure of health-related quality of life that has been widely used among the homeless population.[58] The EQ-5D-3L includes five 3-level items concerning mobility, self-care, usual activities, pain/discomfort, and anxiety/depression that are weighted to produce a single utility score between 0 and 1. The Visual Analog Scale (VAS) of the EQ-5D-3L will also be included, which will allow participants to rate their overall health, mental health, and physical health from 0 to 100.
Medication Adherence/ Barriers to Medication Adherence	**Morisky Medication Adherence Scale-8** The MMAS-8 is the most accepted self-reported measure for medication-taking behavior that has been used among disadvantaged patients and those with chronic illnesses.[59,60] The MMAS-8 consists of 8 items, the first 7 of which are yes/no questions, and the last of which is a 5-point Likert-scale rating.[61] Each ‘‘no” response is rated as ‘‘1” and each ‘‘yes” is rated as ‘‘0” except for item 5, in which each response ‘‘yes” is rated as

	‘‘1” and each ‘‘no” is rated as ‘‘0”. For item 8, if a patient chooses response ‘‘0”, the score is ‘‘1” and if they choose response ‘‘4”, the score is ‘‘0”. Responses ‘‘1, 2, 3” are respectively rated as ‘‘0.25, 0.75, 0.75”. Total MMAS-8 scores can range from 0 to 8 and have been categorized into three levels of adherence: high adherence (score = 8), medium adherence (score of 6 to 8), and low adherence (score< 6). If a participant answers “yes” to question 2 (in the past 2 weeks, were there any days you did not take your medications), the participant will be asked about reasons for non-adherence using a questionnaire developed by our team specifically for homeless adults.[62]
Care Transition	**Care Transitions Measure-3** The most widely used measure of care transition quality is the Care Transition Measure (CTM).[63–65] The CTM-3 is an abbreviated version of the original CTM-15, which measures the extent to which the healthcare team accomplished essential care processes in preparing the patient for discharge and participating in post-hospital self-care activities. The CTM-3 consists of 3 items with a 4-point scale with responses ranging from “Strongly Disagree” (1) to “Strongly Agree” (4) to the following questions: **-**During this hospital stay, staff took my preferences into account in deciding what my healthcare needs would be when I left. -When I left the hospital, I had a good understanding of the things I was responsible for in managing my health. -When I left the hospital, I clearly understood the purpose for taking each of my medications Items are scored by summing the responses and then linear transforming to a 0-100 range.
Competing Priorities	**RAND Course of Homelessness Scale** Developed specifically for homeless populations[12], the RAND scale is a 5-item index of self-reported difficulty in meeting the following subsistence needs over the past 30 days: frequency of difficulty in finding shelter, enough to eat, clothing, a place to wash, and a place to use the bathroom. Possible responses to each item are never (1), rarely (2), sometimes (3), or usually (4) with total scores between 5-20.

Honorariums

Participants will be provided honorariums to compensate them for their time. Participants will be given a $20 Tim Horton's gift card for their participation in the baseline interview. Gift cards are a suitable form of honorarium for the baseline interview given that cash may incentivize patients to leave the hospital prematurely. Tim Horton's is an accessible café with various locations both within the hospital and in the community. Upon completion of the 30-day interview, participants will be compensated with an honorarium of $40 and the cost of round-trip public transportation fare (if the participant traveled to the interview). This honorarium will be paid either as cash after the interview, cash for pick-up at a later day, e-transfer, or mailed cheque.

Chart Review

At patient discharge, a discharge chart review will be conducted using patient charts from St. Michael's Hospital (Discharge Chart Review, Appendix C2). At 180-days post-discharge, data will be collected from patient charts from St. Michael's Hospital, St. Joseph's Hospital, Toronto General Hospital, Toronto Western Hospital, Mount Sinai Hospital, and Michael Garron Hospital (180-Day Chart Review, Appendix C5). Data on the number and nature of interactions between the Homeless Outreach Counsellor and participants, community service providers, and healthcare team will be collected from the Homeless Outreach Counsellors during the 180-day chart review. Finally, during the 180-day chart review, the research team will contact the participant's PCP (PCP Questionnaire, Appendix C4) and other healthcare providers to confirm appointment attendance.

ICES Linkage

Data linkage will be conducted at the Institute for Clinical Evaluation Sciences (ICES), where population-based health information is available at the patient level for all Ontarians using

formal health services. Health service use will be examined in the National Ambulatory Reporting System (NACRS), the Discharge Abstract Database (DAD), the Ontario Mental Health Reporting System (OMHRS), and the Ontario Health Insurance Plan (OHIP) for PCP visits, ED visits and inpatient hospitalizations. This project will attain health service use data for all consenting participants from 3 years prior to the index admission to 1 year following index admission discharge.

The following variables will be ascertained using chart review and administrative data:

Domain	**Variable**
Sociodemographic Variables	- Age - Sex
Hospitalization characteristics	- Admission date - Admitting diagnosis - Outpatient specialties listed
	- Discharge date - Length of index hospital stay - Whether the patient left against medical advice - Discharge diagnoses - Comorbidities list - Charlson Comorbidity Index Score[66] - Number of medications prescribed at discharge - Non-PCP healthcare appointments made and reported in discharge summary - Whether a PCP was copied on discharge summary
Prior Healthcare Use	- Hospitalizations and ED visits to all study hospitals combined in the past year • Dates of hospital visit, length of stay, and reason for admission - Hospitalizations and ED visits to any hospital in Ontario combined in the past year • Dates of hospital visit, length of stay, and reason for admission -Dates of PCP visits in Ontario in the past year
Alcohol and Substance Use	- Alcohol: non-drinker vs current drinker; if yes, how many drinks per day on average - Illicit drug use: none vs current use; if yes, which drugs (open response)

Healthcare Use Post-Discharge	- Hospitalizations and ED visits to all study hospitals combined in the 30-, 90-, and 180-days following discharge • Dates of hospital visit, length of stay, and reason for admission - Hospitalizations and ED visits to any hospital in Ontario combined in the 30-, 90-, and 180-days following discharge • Dates of hospital visit, length of stay, and reason for admission -Dates of PCP visits in Ontario 180-days following discharge -Number of healthcare (non-PCP) appointments from the discharge summary the patient attended 180-days following discharge • Name of healthcare provider, specialty, location, and date of appointment
Mortality	-Date of participant death -Mode of mortality verification - Note that the research team will also contact community organizations to ascertain possible participant mortality if participants are not reachable and such data is not available through chart review and administrative databases

Data Analysis

All analyses will follow the intention-to-treat principle. Sample characteristics will be summarized by descriptive statistics (mean, standard deviation, median, interquartile range, and proportion). We will also construct graphs (histograms, box plots, scatterplots, spaghetti plots) to explore relationships and estimate correlations between selected participants' characteristics and outcomes. Descriptive comparisons between group baseline characteristics and outcomes will be performed with χ^2 or Fisher exact tests for categorical variables and with t-tests or Wilcoxon rank sum tests for continuous or count variables.

Primary Outcome

The primary analysis will be performed using the χ^2 test to compare two independent proportions of 14-day PCP follow-up. The difference in proportions (risk difference, RD) and 95%

confidence interval (CI) will be estimated using Wald's method.[67] Two secondary analyses will be conducted. The first is a log-binomial regression model including the intervention arm indicator as the covariate. The risk ratio (RR) and 95% CI will be estimated from the model. The second is a logistic regression model including the intervention arm indicator as the covariate. The odds ratio (OR) and 95% CI will be estimated from the model.

To explore potential subgroup effects, we will construct multivariable logistic models for the primary outcome including each of the following pre-specified co-variates, one-at-a-time and with corresponding interaction terms with the intervention arm: age, sex, current illicit drug use, current risky alcohol use[68], Charlson Comorbidity Index Score, and prior acute healthcare use for a mental health reason.

Secondary Outcomes

For the composite all-cause hospital readmission or mortality binary outcomes within 30-, 90- and 180-days post-discharge, we will use logistic regression models to estimate odds ratios and 95% CIs using the outcomes as the dependent variables and intervention arm indicator as the covariate. For the count outcomes (number of ED visits and number of days in the hospital within 30-, 90- and 180-days post-discharge), we will use Poisson regression models or negative binomial regression models (if over-dispersion is suggested by the data) to estimate rate ratios and 95% CIs using the outcomes as the dependent variables and the intervention arm indicator as the covariate. For CTM-3 score (cross-sectional continuous outcome), we will use a linear regression model using the outcome as the dependent variable and the intervention arm indicator as the covariate. For competing priorities score at baseline and time of the 30-day interview

(longitudinal continuous outcome), we will use generalized estimating equation (GEE) linear regression models. The models will include the intervention arm indicator, time (baseline versus time of 30-day interview), and the interaction of intervention arm by time. A significant interaction will indicate that the change in competing priorities score from baseline is different between the study groups. This difference and 95% CI will be estimated.

Exploratory Outcomes

For binary outcomes (leaving against medical advice at discharge, connecting to a case manager at the time of the 30-day interview, and attending any non-PCP healthcare appointment noted in the discharge summary within 180-days post-discharge), we will use logistic regression models to estimate odds ratios and 95% CIs using the outcomes as the dependent variable and intervention arm indicator as the covariate. For MMAS-8 score at the time of the 30-day interview (cross-sectional continuous outcome), we will use a linear regression model using the outcome as the dependent variable and the intervention arm indicator as the covariate. For longitudinal continuous outcomes (EQ5D VAS and 3L health status scores at baseline and time of the 30-day interview), we will use GEE linear regression models. The models will include the intervention arm indicator, time (baseline versus time of the 30-day interview), and the interaction of intervention arm by time. Significant interactions will indicate that the changes from baseline are different between the study groups. These differences and 95% CIs will be estimated. For time to all-cause hospital readmission or mortality after index discharge (time to event outcome), we will perform survival analyses. Cumulative event rates will be calculated with the Kaplan-Meier method, with event or censoring times calculated from the date of

discharge. Differences in Kaplan-Meier survival curves between the intervention arms will be assessed using the log-rank test.

Finally, we will also consider any missing data and will perform multiple imputations as sensitivity analyses if indicated.[69] All analyses will be conducted using R (Version 3.6.3) or STATA (Version 16). All statistical tests will be two-sided and a p-value of 0.05 or less will indicate statistical significance. Adjustments will not be conducted for multiple comparisons.

Fidelity

Fidelity of the intervention will be assessed based on whether or not services provided by the Homeless Outreach Counsellors were consistent with the outlined Theory of Change (Appendix K). More specifically, Homeless Outreach Counsellors should meet the following five groups of activities and outputs:

1. Make connections and referrals to community-based providers
2. Support and advocate for patients during hospital stay and discharge process
3. Support patient with health care-related matters during post-discharge period
4. Support patient with social-related matters during post-discharge period
5. Transfer patient-related information to other health care providers and community-based providers

This information will be obtained by research assistants from charts maintained by the Homeless Outreach Counsellors.

Patient Safety

This study will not have a Data and Safety Monitoring Board (DSMB). The Navigator program is unlikely to cause any harm to participants and so a DSMB is not necessary. No interim analysis of data is anticipated.

Data Retention

The research team will make every effort to keep personal health information private and confidential in accordance with all applicable privacy legislation, including the Personal Health Information Protection Act (PHIPA) of Ontario. Any health information that is recorded for study purposes will be de-identified by using a random unique study identifier number instead of any personally identifying information and stored in a Master Linking Log. This information will only be used to get in touch with participants and access health records with participant consent. It will only be seen by research staff who are not connected to any part of participants' care and will stay at St. Michael's Hospital's secure computer server in a password protected file. Only the designated member of the Survey Research Unit will be in control of the Master Linking Log.

At each interview, responses will be collected using tablets with an electronic web version of SNAP Professional Software. All of the electronic data will be kept on a secure server at St. Michael's Hospital in an unreadable format for anyone outside of the study. Only authorized members of the research team will have access to the interview data. All study information will be kept for a period of 7 years from the end of the study and then destroyed. The Principal Investigator will protect participant records and keep all information confidential to the greatest extent possible by law.

Research staff may use texting and email to contact participants, if they indicated on their Contact Information Form that they wished to be contacted in this way. There is no obligation to text or email – participants may always contact the research team by phone or through their Homeless Outreach Counsellor. The research team will not collect any participant personal health information through email or texting. In the consent form, participants are advised that email and text messages are not secure modes of communication, asked not to send any personal health information via text or email, and directed not to use text or email in emergency situations. Research staff will only use a participant's first name in a text message. If the research team does receive personal health information or a notice of an emergency by text or email, the research team will follow up with a phone call.

Participants will be asked if they are interested in being contacted regarding additional related research for 3 years after the completion of the study. If so, participant contact information will be maintained for this time period. If not, it will be destroyed after study completion.

Study Limitations

Several limitations of the proposed study can be noted. First, the study is taking place in a single urban center in Ontario and findings may not be generalized to other contexts with unique challenges in supporting care transitions for individuals experiencing homelessness. Therefore, findings from this initial study should inform multi-site randomized controlled trials across Canada and other countries that are tailored to local contexts. Second, due to the nature of the intervention, participants and the participants' circles of care are not blinded to participant

assignment.[70,71] Knowledge of participant assignment might affect clinical course in the hospital and patient behaviour post-discharge. For example, care teams might be more inclined to discharge a participant in the intervention arm earlier knowing that post-discharge supports are available to the participant. However, the research team and Homeless Outreach Counsellors will actively minimize this potential bias by emphasizing the clinical equipoise surrounding the effectiveness of the Navigator program in improving post-hospital outcomes. Finally, given the recent COVID-19 pandemic[72], participants may experience barriers in engaging with the Homeless Outreach Counsellors and attending in-person interviews. However, this study has been designed to allow for remote encounters with participants and the Homeless Outreach Counsellors have been trained to communicate and work remotely with participants.

Research Team

The research team is led by Dr. Stephen Hwang (Principal Investigator) and includes Dr. Vicky Stergiopoulos, Dr. Rosane Nisenbaum, Dr. Anita Palepu, Dr. Gabriel Fabreau, and Dr. Kerry McBrien (Study Investigators).

Dr. Stephen Hwang, MD, MPH, is a clinician-scientist, the Director of the Centre for Urban Health Solutions at St. Michael's Hospital, and a Professor of Medicine at the University of Toronto. He has an outstanding track record of leading interdisciplinary research teams and conducting studies to improve the health of individuals experiencing homelessness. Dr. Vicky Stergiopoulos, MD, MHSc, is a clinician-scientist, the Physician-in-Chief at the Center for Addiction and Mental Health, and Professor and Vice Chair, Clinical and Innovation in the Department of Psychiatry at the University of Toronto. Her expertise includes mental health

services research, including the design, implementation, and evaluation of interventions for individuals experiencing homelessness using both qualitative and quantitative methods. Dr. Rosane Nisenbaum, PhD, is a Senior Biostatistician at the Centre for Urban Health Solutions and an Assistant Professor at the University of Toronto. She has extensive experience designing and analyzing datasets from intervention studies to improve health and housing outcomes for individuals experiencing homelessness. Dr. Anita Palepu, MD, MPH is the Providence Health Care Head of Medicine and a Professor and Eric Hamber Chair of Medicine at the University of British Columbia. She is a General Internal Medicine Specialist and conducts her research at the Centre for Health Evaluation and Outcome Sciences and has a research program that falls under the broad umbrella of urban health research with a particular interest in the health outcomes of individuals experiencing homelessness. Dr. Gabriel Fabreau, MD, MPH, is a clinician-scientist, Assistant Professor in the Departments of Medicine and Community Health Sciences at the University of Calgary, and an active member of the O'Brien Institute for Public Health. He is a practicing internal medicine specialist with clinical and academic interests in refugee health, socially vulnerable populations, and designing health system innovations for socially vulnerable populations. Dr. Kerry McBrien, MD, MPH, is an Associate Professor in the Departments of Family Medicine and Community Health Sciences at the University of Calgary. She is a clinician-scientist with an active practice in family medicine. Her research focuses on health services and health economics, with a specific interest in models of care that can improve the quality and efficiency of chronic disease management in primary care. Dr. Angela Cheung, MD, PhD, is a Senior Scientist at University Health Network and Professor of Medicine at the University of Toronto. She is a clinician-scientist with broad research interests and particular expertise in clinical epidemiology, knowledge translation, and health services research. Dr.

Matthew To, MD, is a physician and researcher in the Departments of Family and Community Medicine at St. Joseph's Health Centre. He has particular expertise in research surrounding homelessness, primary care, and public health.

Research Staff

The Survey Research Unit at the Centre for Urban Health Solutions (St. Michael's Hospital) will provide research staff for study recruitment and data collection. The Survey Research Unit has completed multiple projects involving individuals experiencing homelessness at St. Michael's Hospital. Cheryl Brown is the Research Project Manager for multiple projects within the Survey Research Unit. Cheryl has many years of research management experience in the healthcare sector. Rebecca Brown is a Research Coordinator in the Survey Research Unit who coordinates the day-to-day operations of multiple projects. Her work centers around quantitative and qualitative data collection, interviewing, and thematic coding. Rebecca is also an experienced interviewer and has conducted a large number of interviews with individuals experiencing homelessness. Michael Liu is a Medical Student and Research Coordinator at the MAP Centre for Urban Health Solutions. Michael has experience at St. Michael's Hospital with quantitative project planning, data collection, and data analysis, with a particular focus on homelessness, health services, and outcomes research. Kate Francombe Pridham is a Research Coordinator at the MAP Centre for Urban Health Solutions that has been developing and implementing the Navigator program. Kate has experience at St. Michael's Hospital with quantitative and qualitative project management, data collection, and data analysis, with a particular focus on mental health and homelessness studies.

Risks and Benefits

Risks

Involvement in this research poses no to minimal risks to participants. The baseline and 30-day interviews do not involve questions that are anticipated to cause emotional distress among participants. There is still a possibility that some participants may find certain interview questions to be challenging or uncomfortable. However, participants may choose to not answer specific questions. Participants may withdraw from the study at any point in time. Should an individual choose to withdraw from the study entirely, they will keep any honorariums, still have access to usual care, and can request that all information collected from them to that point be destroyed. The Study Investigators bring extensive experience in the design, implementation, and evaluation of interventions for the target population, providing an excellent foundation for early identification and prompt response to potential emerging challenges.

Benefits

Study participants who are assigned to the intervention arm will receive the Navigator program and may directly benefit from the services of the Homeless Outreach Counsellors. Study participants in the usual care arm will not receive any direct benefits

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